General

Guideline Title

Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44).

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Feb. 63 p. (Technology appraisal guidance; no. 304).

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Clinical Excellence. Guidance on the use of metal on metal hip resurfacing arthroplasty. London (UK): National Institute for Clinical Excellence (NICE); 2002. 19 p. (Technology appraisal guidance; no. 44).

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Prostheses for total hip replacement and resurfacing arthroplasty are recommended as treatment options for people with end-stage arthritis of the hip only if the prostheses have rates (or projected rates) of revision of 5% or less at 10 years.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

End-stage arthritis of the hip

Guideline Category

Technology Assessment

Treatment

Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Orthopedic Surgery

Rheumatology

Surgery

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the clinical effectiveness and cost-effectiveness of total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip

Target Population

People with pain or disability resulting from end-stage arthritis of the hip for whom non-surgical management has failed

Interventions and Practices Considered

Total hip replacement and resurfacing arthroplasty

Major Outcomes Considered

- Clinical effectiveness
  - Mortality
  - Validated functional/pain and health related quality of life total scores
  - Revision rate
  - Implant survival rate
  - Femoral head penetration rate (measure of prosthesis movement)
  - Adverse events
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Warwick Evidence Division of Health Sciences, Warwick Medical School, University of Warwick (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Identification of Studies

Initial scoping searches were undertaken in Medline in October 2012 to assess the volume and type of literature relating to the assessment question. The scoping searches also informed development of the final search strategies (see Appendix 2 in the ERG report [see the "Availability of Companion Documents" field]). An iterative procedure was used to develop these strategies with input from clinical advisors and previous Health Technology Assessment (HTA) reports. The strategies have been designed to capture generic terms for arthritis, total hip replacement (THR) and resurfacing arthroplasty (RS).

Search Strategies

Final searches were undertaken in November and December 2012 (see Appendix 2 in the ERG report) and were date-limited from 2002 (the date of the most recent NICE guidance in this area). Searches of the clinical effectiveness literature were restricted to randomised controlled trials (RCTs) and systematic reviews; additional searches were undertaken to capture literature relating to costs, resources use, utilities, cost-effectiveness, cost-effectiveness models and registries to inform the survival and cost-effectiveness analysis.

The following main sources were searched to identify relevant published and unpublished studies and studies in progress:

- Electronic bibliographic databases
- Contact with experts in the field
- References of included studies
- Screening of relevant Web sites

The following databases of published studies were searched: MEDLINE; MEDLINE In-Process & Other Non-Indexed Citations; The Excerpta Medica database (EMBASE); Science Citation Index and Conference Proceedings; The Cochrane Library (specifically Cochrane Database of Systematic Reviews; Cochrane Central Register of Controlled Trials [CENTRAL]; Database of Abstracts of Reviews of Effectiveness [DARE]; National Health Service Economic Evaluation Database [NHS EED], HTA database); Current Controlled Trials; ClinicalTrials.gov; UK Clinical Research Network (UKCRN) Portfolio Database. The search strategies were initially developed for MEDLINE and were adapted as appropriate for other databases.

The reference lists of included studies and relevant review articles were checked and the following websites of hip implant manufacturers were screened for relevant publications:

- Amplitude
- Biomet
- B Braun/Aesculap
- Comis Orthopaedics
- Corin
- DePuy
- Exactech

- Finsbury
- Joint Replacement Instrumentation (JRI)
- Implantcast
- Implants International
- Lima WG Healthcare
- Mathys Orthopaedics
- Medacta UK
- Othodynamics
- Peter Brehm
- SERF dedienne santé
- Smith & Nephew
- Stanmore Implants Worldwide
- Stryker
- Symbios SA
- Waldemar Link
- Wright Medical UK
- Zimmer

Grey literature searches were undertaken using Google and the online resources of the following regulatory bodies, health services research agencies and professional societies:

- British Hip Society
- British Orthopaedic Association
- Orthopaedic Research UK
- Orthopaedic Data Evaluation Panel (ODEP)
- National Joint Registry for England and Wales (NJR)
- Arthritis Research UK
- Cochrane Musculoskeletal Group
- Arthritis Care
- UK Medicines and Healthcare Products Regulatory Agency (MHRA)
- American Association of Hip and Knee Surgeons
- American Academy of Orthopedic Surgeons
- The Hip Society
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh

All bibliographic records identified through the electronic searches were collected in a managed reference database.

See Sections 6.1.3 and 6.1.4 of the ERG report (see the "Availability of Companion Documents" field) for inclusion and exclusion criteria.

Study Selection Process

All retrieved records were collected in a specialised database. All duplicate records were identified and removed. Two reviewers pilot-tested an a priori screening form based on the predefined study eligibility criteria. Afterwards, two independent reviewers applied the same inclusion/exclusion criteria and screened all identified bibliographic records for title/abstract (level I) and then for full text (level II). Disagreements over eligibility were resolved through consensus or by a third party reviewer. Reasons for exclusion of full text papers were documented. The study flow was documented using a PRISMA diagram.

Cost-effectiveness

Identification of Studies

Initial scoping searches were undertaken in MEDLINE in October 2012 to assess the volume and type of literature relating to the assessment question. These scoping searches also informed development of the final search strategies (see Appendices 1 and 2 in the ERG report [see the "Availability of Companion Documents" field]). An iterative procedure was used to develop these strategies with input from clinical advisors and previous HTA reports. The strategies have been designed to capture generic terms for arthritis, THR and RS. Searches were limited by the addition of economic and quality of life terms, which were selected with reference to previous research.

Searches were date-limited from 2002 (the date of the most recent NICE guidance in this area). The searches were undertaken in November 2012 (for exact search dates, see Appendix 2 in the ERG report [see the "Availability of Companion Documents" field]).

All bibliographic records identified through the electronic searches were collected in a managed reference database.

The following main sources were searched to allow for identification of relevant published and unpublished studies and studies in progress:

Searching of electronic bibliographic databases, including research in progress
Scrutiny of references of included studies

The following databases of published studies were searched: MEDLINE; MEDLINE In-Process & Other Non-Indexed Citations; EMBASE; Science Citation Index and Conference Proceedings; The Cochrane Library (specifically Cochrane Database of Systematic Reviews, CENTRAL, DARE, NHS EED, HTA database); and CEA Registry (Articles).

The following databases of research in progress were searched: Current Controlled Trials; ClinicalTrials.gov; UKCRN Portfolio Database; and NLM Gateway (Health Services Research Projects in Progress [HSRProj]).

The reference lists of included studies were checked for additional studies.

See Section 6.5.2 of the ERG report for inclusion and exclusion criteria (see the "Availability of Companion Documents" field).

Assessment of Eligibility

All retrieved records were collected in a specialist database and duplicate records were identified and removed. An initial sift was undertaken by one reviewer to exclude clearly non-relevant records using the following exclusion criteria:

- Non-hip only
- Animals
- Children
- Surgery due to hip fracture only
- Non-English full-text

This was followed by a formal sift by title and abstract by two reviewers using the inclusion/exclusion criteria. All identified, relevant studies were read in full by two reviewers to identify eligible studies. Disagreement was resolved by a third reviewer. Reasons for exclusion of full text papers were documented. The study flow was documented using a PRISMA diagram.

See Section 6.8 of the ERG report for registries methods (see the "Availability of Companion Documents" field).

Number of Source Documents

Clinical Effectiveness

A total of 2,469 records were screened of which 37 were included, representing 16 randomised controlled trials (RCTs) and 8 systematic reviews.

Cost-effectiveness

1,664 records were screened. 66 studies were included in the narrative review and 4 of the 11 core studies identified provided relevant date for the model in terms of costs and utilities.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

Rating Scheme for the Strength of the Evidence

Not stated

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Warwick Evidence Division of Health Sciences, Warwick Medical School, University of Warwick (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Quality Assessment Strategy

Two reviewers independently assessed the risk of bias of individual studies using validated tools (see Appendix 3 in the ERG report [see the "Availability of Companion Documents" field]). Any disagreements between the two reviewers were resolved by a third reviewer through a discussion.

Randomised controlled trials (RCTs) were assessed using the Cochrane Collaboration Risk of Bias tool (ROB) which covers the following domains of threat to internal validity: selection bias (randomisation sequence generation, treatment allocation concealment), performance bias (blinding of participants/personnel), detection bias (blinding of outcome assessors), attrition bias (incomplete outcome data), reporting bias (selective outcome/analysis reporting), and other pre-specified bias (e.g., funding source, adequacy of statistical methods used, type of analysis [Intention-to-treat/Per protocol], imbalance in the distribution of baseline prognostic factors between the compared treatment groups). The risk of bias assessment results fall into three distinct categories of high, low, and unclear risk of bias. For each RCT, the risk of bias for performance, detection, and attrition bias domains was assessed for *a priori* defined groups of subjective (e.g., patient-administered clinical and functional scores) and objective (e.g., mortality, revision, survival, radiography result, complications) outcomes separately. Afterwards, the within-study summary risk of bias rating across all the domains was derived for subjective and objective outcomes separately. The decision for determining the within-study summary risk of bias was based on the ratings prevailing for selection, performance, and detection bias domains. At data synthesis stage, the across-study average summary risk of bias was determined and assigned to each outcome of interest.

Methodological quality of included systematic reviews was assessed with the AMSTAR tool which covers the following domains: a) research question, b) inclusion/exclusion criteria, c) search strategy (at least two major electronic databases), d) data extraction by independent reviewers, e) assessment of risk of bias by independent reviewers, f) consideration of risk of bias in the analysis, g) exploration of heterogeneity, and h) publication bias. For convenience of presentation, the methodological quality of each systematic review was graded according to the number of items satisfied as follows: high (range: 9–11), medium (range: 5–8), and low (range: 0–4).

Grading Overall Quality of Clinical Effectiveness Evidence

The overall quality of evidence for each pre-selected (i.e., gradable) outcome across studies was assessed using the systematic approach developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group (http://www.gradeworkinggroup.org).

The GRADE approach indicates levels of confidence in the observed treatment effect estimate(s), which is categorized as high, moderate, low, or very low. The grading of overall quality of evidence for each gradable outcome is based on assessments across five domains: a) summary risk of bias across studies per gradable outcome (internal validity across studies; study limitations), b) consistency of results (heterogeneity), c) directness of the evidence (applicability of the results; indirect treatment comparisons), d) precision of the results (the width of 95% CI around the estimate), and e) publication/reporting bias (detection of asymmetry in the funnel plot; selective outcome reporting). The definitions and explanation of the grading levels and the grading process across the five domains are presented in Sections 6.4.3 and 6.4.6 of the ERG report (see the "Availability of Companion Documents" field).

The gradable outcomes, selected according to their meaningfulness and importance for decision-making, were the following: Harris Hip score, Western Ontario and McMaster Universities Arthritis Index (WOMAC) score, revision, mortality, femoral head penetration rate, and implant dislocation.

Data Extraction Strategy

The relevant data were extracted from included studies independently by one reviewer using a data extraction form informed by the NHS Centre for Reviews and Dissemination (CRD). The extracted data were cross checked by a second reviewer. Uncertainty and/or any disagreements with the second researcher were resolved by discussion. The extracted data were entered into summary and full extraction tables (see Appendices 4 and 5 in the ERG report). The extracted information included the following:

- Study characteristics (i.e., author's name, country, design, study setting, sample size, funding source, duration of follow-up, information relevant to risk of bias assessment such as generation of randomization, allocation concealment, blinding, completeness of outcome ascertainment, patient withdrawals/attrition for randomised trials; for observational studies and non-randomised trials, information on potential confounding was additionally ascertained)
- Patient baseline characteristics (i.e., inclusion/exclusion criteria, number of enrolled/analysed participants, age, race, gender, body mass index, underlying conditions, concomitant conditions, co-interventions, disability, activity levels, function, pain intensity, and quality of life, and disease-specific measures such as the Oxford Hip Score, and Harris Hip Score)
- Experimental treatment characteristics (e.g., type - total hip replacement [THR], resurfacing arthroplasty [RS]; training/experience of the operator, post-operative rehabilitation staff; method of fixation – cemented, cementless, hybrid; bearing surface material – metal-on-metal, ceramic-on-ceramic; metal-on-polyethylene, femoral head size; the name/brand and country of manufacturer; post-operative rehabilitation)
- Outcome characteristics (e.g., definition; timing of measurement; scale of measurement - dichotomous, continuous; measures of association – mean difference, risk ratio, odds ratio, hazard ratio). Statistical test results and measures of variability were also extracted (standard deviation, 95% confidence intervals [CIs], standard error, p-values)

Any additional relevant information found in multiple publications of included studies was also extracted. For studies of clinical effectiveness where summary measures and 95% CIs for the association between the treatments were not reported, mean differences with 95% CIs were calculated, if data allowed (t-tests for independent samples and using continuous outcomes and risk ratios for dichotomous outcomes). No risk ratios and 95% CIs were estimated for individual studies which observed zero events in one or both treatment arms. The 95% CIs and standard errors were used to derive standard deviations or vice versa. All calculated parameters were entered into the data extraction sheets.

Data Management

Study, treatment, population, and outcome characteristics were summarised in text, evidence, and summary tables. The study results were compared qualitatively and quantitatively in text and summary tables. For each outcome of interest, the effectiveness of treatments reported in individual studies was compared as follows:

- Different types of primary THR compared with each other for people who are not suitable for hip RS
- Different types of primary THR compared with RS for people in whom both procedures are suitable

Meta-analysis

The decision to pool individual study results was based on a degree of similarity with respect to methodological and clinical characteristics of studies under consideration (e.g., design, population, comparator treatment, and outcome). Estimates of post-treatment mean difference (MD) for continuous outcomes and risk ratios (RR) for binary outcomes (except for rare events) of individual studies were pooled using a DerSimonian and Laird random-effects model (DerSimonian & Laird, 1986). The choice of this model was based on the assumption that some residual clinical and methodological diversity will exist across pooled studies. Dichotomous outcomes with low event rates (5.0%-10.0%) were pooled as RR using a Mantel-Haenszel fixed-effects model. Dichotomous outcomes for studies with very low event rates (≤5.0%) or zero events in one of the treatment arms were pooled as odds ratio (OR) using a Peto fixed-effects model.

Trials were not pooled if the mean and/or standard deviation for the continuous outcome of interest could not be ascertained.

See Section 6 in the ERG report (see the "Availability of Companion Documents" field) for additional information on analytical methods used.

Cost-effectiveness

Data Abstraction

Data extraction was carried out in two stages by one reviewer using the data extraction sheets (see Appendices 11–13 in the ERG report [see the "Availability of Companion Documents" field]) and checked by a second reviewer. Stage one considered all eligible studies and stage two considered studies assessed for usefulness to populate the economic model. Stage one data extraction included the following:

- Study characteristics (i.e., author's name, country, design, study aim, type of economic evaluation [i.e., cost-effectiveness, cost-utility

analysis], perspective [e.g., societal, health care payer, patient] and study currency)
- Patient characteristics (i.e., number of participants, age, gender, osteoarthritis)
- Outcomes (i.e., utilities, resources use and cost [both direct and indirect], incremental cost-effectiveness ratios)

Data extraction also included the overall study conclusion and a comment on the type of data included in the studies that are relevant for the economic model. Studies were subsequently categorised by topic (THR or RS) and outcomes (costs or utilities) and cost studies were also ordered by year and date using the following hierarchy:

Cost

1. UK study ≥2008
2. UK study <2008
3. Non-UK study ≥2008
4. Non-UK study <2008

Utility studies were ordered by study size and "patient reported utility data" (utilities derived prospectively using patient questionnaires or from databases that prospectively collected utilities) using the following hierarchy:

Utilities

1. >100 THR/RS patients and primary data
2. <100 THR/RS patients and primary data
3. >100 THR/RS patients and secondary data
4. <100 THR/RS patients and secondary data

Second stage data extraction considered cost of THR (cost of device, cost of surgical time/cost of hospital stay), cost of follow up for successful THR, revision THR, follow-up for successful revision THR, costs of RS (cost of device, cost of surgical time/cost of hospital stay), costs of follow up for successful RS, revision RS, follow-up for successful revision RS and utilities at baseline, post-surgery up to 12 months and >12 months. Information on definition of costs, source of costs, cost year and currency was also extracted.

Quality Assessment

The key cost-effectiveness papers which were identified as relevant for the economic model were assessed by one reviewer and checked by a second reviewer using the Consensus on Health Economic Criteria (CHEC) list, while cost-effectiveness studies with economic models were also assessed using the Philips criteria.

See Section 6.8 of the ERG report for registries methods (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The Committee considered the base-case economic analyses presented by the Assessment Group and 1 of the manufacturers (DePuy Synthes).

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee understood that the Guide to the methods of technology appraisal 2008 recommends using publicly available list prices in the reference-case analysis, but noted that the National Health Service (NHS) routinely pays a lower price for hip replacement prostheses because of volume-dependent and locally negotiated discounts. The Committee concluded that there was considerable uncertainty surrounding the prices of prostheses.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee concluded that it was plausible that people who had revision surgery would have a lower quality of life than people who had a successful primary hip replacement. It further concluded that, given the available evidence, it was not possible to determine how use of different types of hip replacement prostheses would affect quality of life.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

Not applicable

What Are the Key Drivers of Cost-effectiveness?

The Committee noted that, in the analyses of cost-effectiveness, the Assessment Group and manufacturer used the average revision rate across category, and that the revision rate was the most important key driver of costs and quality-adjusted life years (QALYs) in the model.

Prostheses become more cost effective the lower the revision rates.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

Incremental cost-effectiveness ratios (ICERs) were not the relevant parameter in determining the recommendations. This was because the ICERs were dependent on the predicted average revision rates of the analysed categories of prostheses, the differences in QALYs between categories were small, and individual brands may have different revision rates from the category average.

How Has the New Cost-effectiveness Evidence That Has Emerged Since the Original Appraisal (TA2 and TA44) Influenced the Current Recommendations?

The Committee concluded that total hip replacement (THR) was more effective and less costly than resurfacing arthroplasty in all analyses, but that the small differences between cemented and cementless prostheses were associated with uncertainty.

The Committee considered making recommendations for particular prostheses categories based on the point estimate reflecting the average revision rate of multiple brands of prostheses within a category. However, it concluded that this would disadvantage individual brands of prostheses with particularly low revision rates and would give an unfair advantage to individual brands with high revision rates within an overall well-performing category.

The Committee concluded that it was appropriate to recommend that a prosthesis should meet a revision rate of 5% or less at 10 years.

See Sections 3 and 4 in the original guideline document for additional information.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Assessment Group conducted a systematic review of randomised controlled trials (RCTs), published systematic reviews and published registry studies of hip replacement procedures. In addition, the Assessment Group analysed individual patient data from national joint registries.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip

Potential Harms

Adverse events associated with hip replacement surgery (total hip replacement or resurfacing arthroplasty) may occur because of complications at the time of surgery or many years afterwards. Complications that may lead to hip replacement revision surgery include prosthesis instability, dislocation, aseptic loosening, osteolysis (bone reabsorption), infection and prosthesis failure.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Service (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has end-stage arthritis of the hip and the doctor responsible for their care thinks that total hip replacement or resurfacing arthroplasty is the right treatment, it should be available for use, in line with NICE's recommendations.
- NICE has developed a costing statement (see the "Availability of Companion Documents" field) explaining the resource impact of this guidance to help organisations put this guidance into practice.
- The Orthopaedic Data Evaluation Panel (ODEP) hosted and facilitated by the NHS Supply Chain will provide information about revision rates for hip prostheses, enabling commissioners in the NHS to comply with this guidance. ODEP coordinates, receives and analyses submissions of long-term performance data from prosthesis manufacturers, used in the UK and internationally. Based on the quality and length of follow-up data, prostheses are rated as per the table below.

Table. Benchmarks Developed by ODEP

Pre-entry	Pre-entry A: Product launched under Beyond Compliance.
	Pre-entry B: Products registered with the National Joint Registry. All primaries and revisions monitored via supplier feedback.
3 years	3A rating: 150 with minimum 3 years' follow-up with actual revision rates of less than 3%. All deaths, loss to follow-up failures and indications for revisions recorded.
	3B rating: Data for a smaller cohort demonstrating less than 3% revision rates at 3 years, and patient time incidence rate (PTIR) or Kaplan–Maier survivorship data showing confidence limits on the data.
5	5A rating:

years	250 patients (with data from beyond the developing centre submitted) with minimum 5 years follow-up with actual revision rates of less than 5%. All deaths, loss to follow-up indications for revisions recorded.
	5B rating: Data for a smaller cohort demonstrating less than 5% revision rates at 5 years, and PTIR or Kaplan–Maier survivorship data showing confidence limits on the data.
7 years	7A rating: 350 patients (with data from beyond the developing centre submitted) with a minimum of 7 years follow-up with actual revision rates of less than 7%. All deaths, loss to follow-up, failures and indications for revisions recorded.
	7B rating: Data for a smaller cohort demonstrating 7% at 7 years, and PTIR or Kaplan–Maier survivorship data showing confidence limits on the data.
10 years	10A* rating: 500 patients (including 3 centres in cohort and including data from beyond the developing centres) with a minimum of 10 years' follow-up with actual revision rates of less than 5% at 10 years (that is, demonstrating survivorship of better than 95%). All deaths, loss to follow-up failures and indications for revision included in data.
	10A rating: 500 patients (including 3 centres in cohort and including data from beyond the developing centres) with a minimum of 10 years' follow-up with a survivorship of better than 90%. All deaths, loss to follow-up, failures and indications for revision included in data.
	10B rating: Data for a smaller cohort demonstrating 10% at 10 years, and PTIR or Kaplan–Maier survivorship data showing confidence limits on the data.

- Both strength of data and length of follow-up are considered when awarding a rating to individual stem and cup components. While the current A and B rating system is to be retained to support international users of the ratings, hip prostheses will need to track towards no more than a 5% revision rate over 10 years to achieve a 10A* rating in line with NICE guidance (implants with a 3A rating, followed by a 5A rating and with a less than 5% revision rate at 7 years are considered on track to meet the 10A* rating). All hip prostheses are expected to progress through benchmarks from pre-entry with, for example, a 5 year submission expected within 3 years following award of a 3-year benchmark. Failure to follow this progression will result in products being de-registered on the ODEP website. In addition, the option to show products at pre-entry following the Beyond Compliance Programme has been included with the introduction of a pre-entry 'A' benchmark.
- When contracts for the purchase of prostheses exist and cannot be changed, the recommendation applies to all new contracts. However, commissioners should explore whether there is flexibility within such contracts to orientate their buying towards prostheses that meet the updated recommended revision rate standard.

Implementation Tools

Audit Criteria/Indicators

Mobile Device Resources

Patient Resources

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Feb. 63 p. (Technology appraisal guidance; no. 304).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2002 Jun (revised 2014 Feb)

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

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Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Clinical Excellence. Guidance on the use of metal on metal hip resurfacing arthroplasty. London (UK): National Institute for Clinical Excellence (NICE); 2002. 19 p. (Technology appraisal guidance; no. 44).

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44). Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Feb. (Technology appraisal guidance; no. 304). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Clarke A, Pulikottil-Jacob R, Grove A, Freeman K, Mistry H, Tsertsvadze A, Connock M, Court R Kandala N-B, Costa M, Suri G, Metcalfe D, Crowther M, Morrow S, Johnson S, Sutcliffe P. Total hip replacement and surface replacement for the treatment of pain and disability resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44). Coventry (UK): Warwick Evidence; 2013. 392 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site .

In addition, benchmarks are available in Section 5 of the original guideline document .

Patient Resources

The following is available:

- Artificial hips and hip resurfacing for end-stage hip arthritis. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Feb. (Technology appraisal guidance; no. 304). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE

Web site .

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